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Robert M Barrett P O Box 1135 Chicago, IL 60690-1135			EXAMINER MOHAMED, ABDEL A	
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Please find below and/or attached an Office communication concerning this application or proceeding.

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**BEFORE THE BOARD OF PATENT APPEALS
AND INTERFERENCES**

Application Number: 09/646,748
Filing Date: December 11, 2000
Appellant(s): BOZA, JULIO

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GROUP 1600

Robert M. Barrett
For Appellant

EXAMINER'S ANSWER

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This is in response to the appeal brief filed 07/03/07 appealing from the Office action mailed 10/16/06.

(1) Real Party in Interest

A statement identifying by name the real party in interest is contained in the brief.

(2) Related Appeals and Interferences

The examiner is not aware of any related appeals, interferences, or judicial proceedings, which will directly affect or be directly affected by or have a bearing on the Board's decision in the pending appeal.

(3) Status of Claims

The statement of the status of claims contained in the brief is correct.

(4) Status of Amendments After Final

No amendment after final has been filed.

(5) Summary of Claimed Subject Matter

The summary of claimed subject matter contained in the brief is correct.

(6) Grounds of Rejection to be Reviewed on Appeal

The Appellant's statement of the grounds of rejection to be reviewed on appeal is correct.

(7) Claims Appendix

The copy of the appealed claims contained in the Appendix to the brief is correct.

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(8) Evidence Relied Upon

5,849,335

BELLEVRE et al.

12-1998

Publication of 100% Whey Protein 5 lbs by Optimum Nutrition (Optimum Nutrition)
Costello's Health Distributor's Fall '97 catalog of Optimum Nutrition 100% whey protein.

(9) Grounds of Rejection

The following ground(s) of rejection are applicable to the appealed claims:

1. Rejection under 35 U.S.C. 102(b)

Claims 1, 2 and 6 are rejected under 35 U.S.C. 102(b) as being anticipated by the product 100% Whey Protein 5 lbs, which is available in the market by Optimum Nutrition (formerly known as Costello's).

The instantly claimed invention as drafted in claims 1, 2 and 6 are broadly directed to methods for increasing glutamine by using whey protein having at least 80% by weight or a protein mixture in Markush format administered to a patient to increase plasma glutamine concentration in stressed mammal, i.e., the term "stressed mammal" is a non-limiting condition (claim 1), to increase muscle glutamine concentrations in mammal generally (claim 2), wherein the protein is hydrolyzed (claim 6).

The product of Optimum Nutrition as evidenced on the cited web site search discloses the superior blend of whey protein isolates, concentrates and hydrolysates, wherein the whey protein isolates as the primary protein source contains 100% whey protein. The cited product is useful as a dietary supplement for the intended purposes of increasing plasma glutamine concentration in stressed mammal or for increasing muscle glutamine concentrations in a mammal. Therefore, the cited product discloses

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the invention substantially as claimed, in the absence of evidence to the contrary the nutritional formulation and its use thereof as disclosed by the product anticipate claims 1, 2 and 6 as drafted.

2. Rejection under 35 U.S.C. 103(a)

Claims 1-16 are rejected under 35 U.S.C. 103(a) as being unpatentable over the product 100% Whey Protein 5 lbs, which is available in the market by Optimum Nutrition (formerly known as Costello's) taken with Ballevre et al. (U.S. Patent No. 5,849,335).

The product of Optimum Nutrition as evidenced on the cited web site search discloses the superior blend of whey protein isolates, concentrates and hydrolysates, wherein the whey protein isolates as the primary protein source contains 100% whey protein. The cited product (i.e., the primary reference) discloses a nutritional composition including a protein source having at least 80% by weight of a whey protein (i.e., with 23 grams of protein in just a one ounce serving). Further, the cited product (the primary reference) discloses a nutritional composition providing 110 Calories per serving, wherein total protein is 23 g, total fat is 1.5 g, and total carbohydrate is 3 g with typical amino acid profile per scoop is cysteine 440 mg, glutamine and precursors 3870 mg, histidine 400 mg, isoleucine 1520 mg, and leucine 2470 mg. The above nutritional composition is used as a dietary supplement.

Furthermore, the claims of the instantly claimed invention are broad because claims 1-16 are directed to methods for increasing glutamine by using whey protein or a protein mixture administered to a patient to increase plasma glutamine concentration in stressed mammal (claim 1), to increase muscle glutamine concentration in mammal

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(claim 2), to use as nutritional/therapeutic composition to a mammal suffering from injured, diseased or under-developed intestines (claim 3), wherein the mammal is a pre-term infant having an under-developed intestines (claim 4), wherein the protein is hydrolyzed (claims 5 and 6) and having the various molecular weights recited in claim 7, wherein the protein source provide energy of the nutritional composition thereof (claims 8, 11 and 14), wherein the nutritional composition further includes a lipid source (claims 9, 12 and 15) and wherein the nutritional composition includes carbohydrate source (claims 10, 13 and 16).

Although, the primary reference teaches the use of a nutritional composition comprising 100% whey protein for dietary supplement, however, the secondary reference of Ballevre et al ('335 patent) teaches a nutritional composition comprising a protein source including whey protein and a protein mixture having the amino acid profile of whey protein which is administered to stressed patients to increase the plasma glutamine concentration, or administered as nutritional support for increasing muscle glutamine concentration in athletes after exercise, or administered to patients suffering from injured or diseased intestines or to maintain the physiological functions of the intestines particularly in under-developed intestines (e.g., a pre-term infant or babies) as disclosed on the abstract; col. 1, lines 44-50; col. 3, lines 1-25; col. 6, lines 13-38; claims 24, 26-28 and 30, thus meeting the limitations of claims 1-4.

Thus, in view of the combined teachings of the prior art, one of ordinary skill in the art would have been motivated to use the already known process of whey protein hydrolysate comprising glutamine for nutritional purpose (i.e., a metabolic process) in

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the known principles of physiology that naturally occurs after intake of food or meal that would result in increasing the plasma glutamine concentration.

On col. 4, the '335 patent discloses the use of nutritional composition wherein the whey protein is hydrolyzed whey protein, the protein source provides about 10% to about 30% of the energy of the nutritional composition, the nutritional composition further includes a lipid source which provides about 20% to about 40% of the energy of the nutritional composition and the lipid source comprises a mixture of medium chain and long chain fatty acids, and as such meet the limitations of claims 5, 6, 8, 9, 11, 12, 14 and 15. The secondary reference also discloses a nutritional composition which further includes a carbohydrate source which provide about 35% to about 60% of the energy of the nutritional composition and as such meet the limitations of claim 10, 13 and 16 (See e.g., col. 2, lines 46-64; col. 4, lines 4-56 and Examples 2-4).

Therefore, given the teachings of the product of primary reference of Optimum Nutrition which teaches the use of nutritional composition of 100% whey protein for dietary supplement, one of ordinary skill in the art would have been motivated at the time the invention was made to adapt the above scheme of the administration of nutritional composition, which contains whey protein (or a protein mixture which stimulates its acid profile) as a protein source for the same purposes (i.e., for increasing glutamine levels in plasma or muscle of a stressed patient, pre-term baby or athletes) of the '335 patent. Further, such features are known or suggested in the art, as seen in the '335 patent, and including such features into the composition/formulation of the

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primary reference would have been obvious to one of ordinary skill in the art to obtain the known and recognized functions and advantages thereof.

Therefore, the combined teachings of the cited references makes obvious the claimed invention because at the time the invention was made based on the combined teachings of the cited references and for the reasons given above, one of ordinary skill in the art would have easily adapt of using the already known process of the whey protein hydrolysate comprising glutamine for nutritional purposes (i.e., a metabolic process), which is a mechanism wherein the sum total of chemical and physical processes within the body related to release of energy by the breakdown of chemical fuel and the use of that energy by the cells for their own work. Thus, the combined teachings of the cited references clearly showing the known principles of physiology that naturally occurs after intake of food or meal that increases plasma glutamine concentration in mammals, increases muscle glutamine concentration in mammal and provides treatment to patients suffering from injured, diseased or under-developed intestines.

Accordingly, claims 1-16 are *prima facie* obvious over the combined teachings of the cited references, because it is an obvious modification of the cited references combined teachings for a nutritional composition including a protein source having at least 80% by weight of a component selected from either whey protein or a mixture which stimulates the amino acid profile of whey protein consisting of approximately 80% to about 90% by weight for nutritional purposes in the manner claimed, absent of sufficient objective factual evidence or unexpected results to the contrary.

(10) Response to Argument

1. Rejection under 35 U.S.C. 102(b)

Appellant has argued that the product disclosed by Optimum Nutrition was not on sale or publicly disclosed before the priority date of the present application because the product disclosed in Optimum Nutrition is not the same product disclosed in Costello's. Further, Appellant asserts that it remains possible that Costello's nutritional product referred by the Examiner does not disclose or suggest a protein source having at least 80% by weight of a whey protein or a protein mixture which stimulates the amino acid profile of whey protein as required, in part, by the present claims. Instead, Costello's nutritional product may also provide additional protein sources besides whey protein that amount to more than 20% of the total protein source. Thus, the Patent Office has failed to demonstrate that *Optimum Nutrition* was on sale before the priority date of the present application (i.e., March 31, 1998). Moreover, the Patent Office has failed to show that any earlier version of the product of *Optimum Nutrition* was identical to that now sold. Accordingly, the rejection of claims 1-2 and 6 under 35 U.S.C. § 102(b) should be reversed because Optimum Nutrition as evidenced by Costello's is not proper prior art.

Contrary to Appellant's arguments and assertion, the Optimum Nutrition as evidenced on the cited web search discloses the superior blend of whey protein isolates, concentrates and hydrolysates, wherein the whey protein isolate as the primary protein source contains 100% whey protein. For evidence, Appellant's attention is directed to the front page of Costello's Health Distributor's 1997 product catalog

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(provided to the Office by Optimum Nutrition) along with a copy of the specific page of the catalog that lists 100% whey protein product (codes 02 288 and 02 289, available in the 2 # size in chocolate and vanilla flavors). Note Optimum Nutrition's description "Like its predecessors, Optimum Nutrition's 100% Whey Protein contains Optimum Nutrition's exclusive, propriety blend of." and their statement "Since the very beginning, Optimum Nutrition's 100% Whey Protein...." taken together these statements support the position that the 100% Whey Protein content of the supplement has not changed since the Fall 1997 catalog description contrary to Appellant's contention. Appellant also urges that the Optimum Nutrition as evidenced by Costello's fails to disclose or suggest every element of claim 1, namely a method for increasing plasma glutamine concentration in a stressed mammal. Appellant's attention is directed to the term "stressed mammal" which is a non-limiting condition because all mammals experience at least some level of stress. The Optimum Nutrition product, namely 100% whey protein is useful as a dietary supplement, and as such would inherently increase plasma glutamine concentration in stressed mammal because of the known principles of physiology that naturally occurs after intake of food or meal, and in the instant case as evidenced by Costello's Health Distributor's 1977 product catalog (code 02 288 and 02 289, available in 2 # size in chocolate and vanilla flavors). Thus, increasing plasma glutamine concentration is considered inherent of the prior art teachings. Therefore, the Patent Office has clearly demonstrated that *Optimum Nutrition* was on sale before the priority date of the present application (i.e., 03/31/98), and as such, the rejection under 35 U.S.C. § 102(b) for claims 1, 2 and 6 should be sustained.

2. Rejection under 35 U.S.C. 103(a)

First, Appellant has argued that one having ordinary skill in the art would not be motivated to combine the cited references to arrive at the present claims. The Examiner has failed to consider the references as a whole and those proteins teaching against or away the combination and from the claimed invention. Instead, the Examiner has improperly attempted to combine references that have different intended purposes and/or distinct mode of operation. As a result, one having ordinary skill in the art would not be motivated to combine Optimum Nutrition as evidenced by Costello's and Ballevre et al. to arrive at the present claims.

The whole premise of Ballevre is that carob protein is rich in glutamine and that its nutritional composition for improving plasma glutamine should include carob protein. Ballevre et al. disclose that carob protein comprises about 40% to about 100% by weight of the protein source of its nutritional composition, which results in the protein source in Ballevre et al. containing a minimum of "about 40%" of the protein source of carob. Because Ballevre et al. teach that it is essential to retain carob protein, it teaches away from a combination with *Optimum Nutrition* that is directed to a product comprising 100% whey proteins. If the proposed modification would render the prior art invention being modified unsatisfactory for its intended purposes, then there is no suggestion or motivation to make the proposed modification.

Second, Appellant has argued that even if combinable, the cited references fail to disclose or suggest all the elements of the claimed invention because Ballevre and Optimum Nutrition as evidenced by Costello's fail to disclose or suggest every element

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of independent claims 1 and 3. For example, Balleve et al. fail to disclose or suggest a method for increasing plasma glutamine concentration in a stressed mammal as required, in part, by claim 1. Balleve et al. also fail to disclose or suggest a method for providing glutamine to a mammal suffering from injured, diseased or under-developed intestines as required, in part, by claim 3.

Further, Balleve et al. is entirely directed to the use of a protein source comprising carob protein, which is rich in glutamine. As a result, it teaches away from Appellant's present claims wherein the protein source contains a low concentration of glutamine (e.g., because the protein source comprises at least 80% by weight whey protein).

Also, Optimum Nutrition as evidenced by Costello's fails to disclose or suggest every element of the claimed invention. For example, Optimum Nutrition as evidenced by Costello's fails to disclose or suggest a method for increasing plasma glutamine concentration in a stressed mammal as required, in part, by claim 1. Optimum Nutrition as evidenced by Costello's fails to disclose or suggest a method for providing glutamine to a mammal suffering from injured, diseased or under-developed intestines as required, in part, by claim 3. In fact, Optimum Nutrition as evidenced by Costello's fails to disclose or suggest administering its compound to any stressed or injured/diseased mammal, for example, to increase its plasma glutamine concentration in accordance with the present claims. Appellant concludes by stating that Appellant has discovered the novel way of increasing glutamine levels in mammals by providing nutritional compositions that have relatively low glutamine levels themselves. Appellant has

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carefully researched the desirability, applicability and levels of protein sources to be effectively used for such increase to occur. Nowhere does Ballevre et al. or Optimum Nutrition recognize or successfully employ administering to a stressed or injured/diseased mammals the claimed nutritional products comprising a protein source having at least 80% by weight of a whey protein or a protein mixture which stimulates the amino acid profile of whey protein to increase glutamine levels in the mammals.

Contrary to Appellant's arguments, the claims of the instantly claimed invention are broad because claims 1-16 are directed to methods for increasing glutamine by using whey protein or a protein mixture administered to a patient to increase plasma glutamine concentration in stressed mammal (claim 1), to increase muscle glutamine concentration in mammal (claim 2), to use as nutritional/therapeutic composition to a mammal suffering from injured, diseased or under-developed intestines (claim 3), wherein the mammal is a pre-term infant having an under-developed intestines (claim 4), wherein the protein is hydrolyzed (claims 5 and 6) and having the various molecular weights recited in claim 7, wherein the protein source provide energy of the nutritional composition thereof (claims 8, 11 and 14), wherein the nutritional composition further includes a lipid source (claims 9, 12 and 15) and wherein the nutritional composition includes carbohydrate source (claims 10, 13 and 16).

The Examiner acknowledges that the primary reference of *Optimum Nutrition* teaches the use of a nutritional composition comprising 100% whey protein for dietary supplement, however, the secondary reference of Ballevre et al. ('335 patent) teaches a nutritional composition comprising a protein source including whey protein and a protein

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mixture having the amino acid profile of whey protein which is administered to stressed patients to increase the plasma glutamine concentration, or administered as nutritional support for increasing muscle glutamine concentration in athletes after exercise, or administered to patients suffering from injured or diseased intestines or to maintain the physiological functions of the intestines particularly in under-developed intestines (e.g., a pre-term infant or babies) as disclosed on the abstract; col. 1, lines 44-50; col. 3, lines 1-25; col. 6, lines 13-38; claims 24, 26-28 and 30. Thus, clearly meeting the limitations of claims 1-4.

On col. 4, the '335 patent discloses the use of nutritional composition wherein the whey protein is hydrolyzed whey protein, the protein source provides about 10% to about 30% of the energy of the nutritional composition, the nutritional composition further includes a lipid source which provides about 20% to about 40% of the energy of the nutritional composition and the lipid source comprises a mixture of medium chain and long chain fatty acids, and as such meet the limitations of claims 5, 6, 8, 9, 11, 12, 14 and 15. The '335 patent also discloses a nutritional composition which further includes a carbohydrate source which provide about 35% to about 60% of the energy of the nutritional composition and as such meet the limitations of claim 10, 13 and 16 (See e.g., col. 2, lines 46-64; col. 4, lines 4-56 and Examples 2-4).

Therefore, given the teachings of the product of Optimum Nutrition which teaches the use of nutritional composition of 100% whey protein for dietary supplement, one of ordinary skill in the art would have been motivated at the time the invention was made to adapt the above scheme of the administration of nutritional composition, which

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contains whey protein (or a protein mixture which stimulates its acid profile) as a protein source for the same purposes (i.e., for increasing glutamine levels in plasma or muscle of a stressed patient, pre-term baby or athletes) of the '335 patent. Further, such features are known or suggested in the art, as seen in the '335 patent, and including such features into the composition/formulation of the primary reference would have been obvious to one of ordinary skill in the art to obtain the known and recognized functions and advantages thereof.

Therefore, the combined teachings of the cited references makes obvious the claimed invention because at the time the invention was made based on the combined teachings of the cited references and for the reasons given above, one of ordinary skill in the art would have easily adapt of using the already known process of the whey protein hydrolysate comprising glutamine for nutritional purposes (i.e., a metabolic process), which is a mechanism wherein the sum total of chemical and physical processes within the body related to release of energy by the breakdown of chemical fuel and the use of that energy by the cells for their own work. Thus, the combined teachings of the cited references clearly showing the known principles of physiology that naturally occurs after intake of food or meal that increases plasma glutamine concentration in mammals, increases muscle glutamine concentration in mammal and provides treatment to patients suffering from injured, diseased or under-developed intestines.

Accordingly, claims 1-16 are *prima facie* obvious over the combined teachings of the cited references, because it is an obvious modification of the cited references

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combined teachings for a nutritional composition including a protein source having at least 80% by weight of a component selected from either whey protein or a mixture which stimulates the amino acid profile of whey protein consisting of approximately 80% to about 90% by weight for nutritional purposes in the manner claimed. Further, the combined references renders obvious the claimed invention because the prior art taken as a whole teaches or suggests the desirability, applicability and levels of protein sources to be effectively used for such increase to occur (i.e., to increase the plasma glutamine concentration), and thus the obviousness of making the necessary combination for the reasons stated above.

Therefore, it is made obvious by the combined teachings of the prior art since the instantly claimed invention which falls within the scope of the prior art teachings would have been obvious because as held in host of cases including *Ex parte Harris*, 748 O.G. 586; *In re Rosselete*, 146 USPQ 183; *In re Burgess*, 149 USPQ 355 and as exemplified by *In re Betz*, "the test of obviousness is not express suggestion of the claimed invention in any and all of the references but rather what the references taken collectively would suggest to those of ordinary skill in the art presumed to be familiar with them". Further, obviousness does not require absolute predictability, *In re Lamberti*, 192 USPQ 278; *In re Miegel et al*, 159 USPQ 716; *In re Moreton*, 129 USPQ 288 but only reasonable expectation of success, *In re Longi*, 255 USPQ 645; *In re Pantzer et al*, 144 USPQ 415; *In re Farnham et al*, 188 USPQ 365.

For the above reasons, it is believed that the rejections should be sustained.

Respectfully submitted,

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September 12, 2007

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